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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/698,341 10/27/00 SORGE

J 25436/1560

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HM12/0815

EXAMINER

HUTSON, R

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/698,341

Applicant(s)

SORGE ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 48-84 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-3, 5, 46 and 47 is/are allowed.
- 6) ☒ Claim(s) 6-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's election with traverse of Group I, Claims 1-47, in Paper No. 8 is acknowledged. As was communicated to Kathleen Williams via Mark Fitzgerald on 8/2/2001, claim 4 was mistakenly grouped with the elected group and should be properly included with unelected group II drawn to a recombinant vector.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4 and 48-84 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: Page 23, line 5, recites "...the conventional deoxynucleotides dATP, dCTP, cGTP and TTP..." It is believed that applicants intended that "TTP" be "dTTP".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Since the use of the *Thermococcus* species JDF-3 is essential to the claimed invention, and this species must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The claimed organisms are not fully disclosed nor have they been shown to be publicly known and freely available. The specification does not disclose a repeatable process to obtain this organism nor is it apparent if it is readily available to the public. The enablement requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the strain *Thermococcus* species JDF-3. Accordingly, it is deemed that a deposit of this strain should have been made in accordance with 37 CFR 1.801-1.809.

If a deposit is/was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application , access to the invention will be afforded to the Commissioner upon request;
2. all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
4. the deposit will be replaced if it should ever become inviable.

Claims 6-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 10-45 are directed to all possible DNA polymerases from *Thermococcus* species JDF-3 DNA that are 3' to 5' exonuclease deficient (claims 6-9 and 17-21) and all recombinant DNA polymerases having a reduced discrimination against non-conventional nucleotides (claims 10, 14, 15, 16 and 22-45) wherein said polymerase is a Family B polymerase(claim 11), wherein said polymerase mutant further comprises a mutation defined in claim 12 or 13 (claims 12 and 13). The specification only provides the representative species encompassed by these claims, wherein said mutant polymerase is from *Thermococcus* species JDF-3 and the mutation is selected from the group consisting of mutations at residues: S345, P410, D141, E143, A485 and L408, of

SEQ ID NO: 2. While it is admitted that applicants disclose a number of mutations, these are not representative of the genus of mutations claimed which encompasses any and all mutations of any Family B or *Thermococcus* species JDF-3 DNA polymerase which results in a decrease in 3' to 5' exonuclease activity or a reduction in discrimination against non-conventional nucleotides. There is no disclosure of any particular structure to function/activity relationship in the claimed genres. The specification also fails to describe additional representative species of these DNA Polymerase mutants by any identifying structural characteristics or properties other than having a decrease in 3' to 5' exonuclease activity or a reduction in discrimination against non-conventional nucleotides, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 (11-15, 43 and 44 dependent from), 16 (17-45 dependent from) and 41 are indefinite in that it is unclear what applicants intent is when reciting "non-conventional nucleotides". Applicants disclose on page 23, lines 1 thru 7, that "DNA polymerase strongly prefers to incorporate the conventional deoxynucleotides dATP, dCTP, cGTP and TTP into DNA polymers; the polymerase is unlikely to progress with an unconventional nucleotide in its binding pocket." While it is clear that dATP, dCTP, cGTP and (d)TTP are considered to be "conventional nucleotides" it is unclear what other nucleotides, if any are also considered to be "conventional". For the purpose of compact prosecution, "conventional nucleotides" are considered to include dATP, dCTP, cGTP and dTTP.

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 10, 11, 14, 15, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Riedl et al. (U.S. Patent No: 5,882,904, filed 8/4/1997).

Riedl et al. teach a mutant *Thermococcus barosii* DNA polymerase with reduced 3'-5' exonuclease activity, wherein said mutant polymerase has a reduced discrimination against dideoxynucleotides or ribonucleotides relative to the wildtype. The specific mutant taught by Riedl et al. comprises the replacement of the native amino acid residue at positions 488, 489, 490, 491 and 493 with a different amino acid relative to the native polymerase. While Riedl et al. do not teach that the disclosed mutants have a reduced discrimination against conjugated nucleotides recited in claim

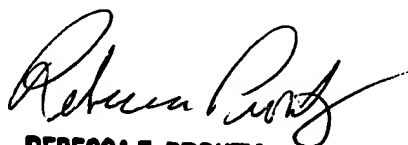
15, this is considered to be an inherent property of the taught mutant polymerase. Riedl et al. further teach the mutation of residue 141 from D to A and mutation of residue 143 from E to A (See column 1, line 63).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Richard Hutson Ph.D.
August 10, 2001


REBECCA E. PROUTY
PRIMARY EXAMINER
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1600